

## REMARKS

Reconsideration and allowance in view of the foregoing amendments and the following remarks is respectfully requested. Upon entry of the present amendment, claims 1-4, 6, 7, 10, 12, 13, 15-17, and 19-39 will be pending. To preserve the arguments presented in the previous response, the Applicant once again reasserts that the Examiner has not established the prima facie case of obviousness. Secondly, the Applicant rebuts the prima facie case of obviousness through the submission of declarations and documents which establish that an embodiment of the present invention has achieved surprising commercial success, resolves a long-felt need in the medical industry, and is being copied by a competitor.

### 1. Failure to Establish a Prima Facie Case of Obviousness

Claims 1-4, 6, 7, 10, 21, and 23-36 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 4,054,207 to Lazure et al. in view of the Applicant's admission of the prior art as evidenced by the Blass et al. article, the Stevens et al. article dated 1997 ("the Stevens 1997 article"), the Stevens et al. article dated 1999 ("the Stevens 1999 article"), the Franck article, further in view of U.S. Patent No. 3,654,746 to Beckers, and U.S. Patent No. 4,597,242 to Hendriks et al., U.S. Patent No. 4,211,338 to Bublitz, further in view of the Seattle Post-Intelligencer article, Wisconsin State J. article, further in view of the San Francisco Examiner article, New Food Products in Japan article, Food Engineering article, further in view of U.S. Patent No. 2,138,241 to Koch et al., U.S. Patent No. 4,165,594 to Corbic, U.S. Patent No. 4,875,620 to Lane, U.S. Patent No. 5,429,262 to Sharkey, U.S. Patent No. 3,390,766 to Stockdale, U.S. Patent No. 3,478,489 to Meisner, and U.S. Patent No. 3,414,414 to Christine et al. Applicant respectfully traverses these rejections for the reasons presented below. As enacted, 35 U.S.C. § 103 of the 1952 Patent Act states the following:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated

by the manner in which the invention was made. The examiner bears the initial burden to present a prima facie case of obviousness.

It is then left to the applicant to rebut the prima facie case. In re Oetiker, 977 F.2d 1443, 24 USPQ 2d 1443, 1447 (Fed. Cir. 1992). It is generally accepted that the prima facie case of obviousness is established when the examiner can provide:

1. one or more references
2. that were available to the inventor,
3. that teach
4. a suggestion to combine or modify the references,
5. the combination or modification of which would appear to be sufficient to have made the claimed invention obvious to one of ordinary skill in the art.

An applicant who is able to prove that the examiner has failed to establish any one of these elements will overcome the examiner's prima facie case of obviousness.

In the present Application, the Applicant has argued unsuccessfully that the Examiner has not adequately established that the cited references teach or suggest the claimed invention. The proposed combination of references could have only resulted from the improper use of hindsight.

The Federal Circuit has outlined the boundaries of obviousness in several significant decisions. In one such decision, Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984), a patent was filed on a hydraulic scrap shear. Two different shears were common in the industry: one for light to medium gauge metal and one for high gauge metal. The patent disclosed a device that was capable of processing both types of scrap in a single moderately sized device. The District Court concluded that the patent "... disclosed and claimed a combination of features previously used in two separate devices." Id. at 1462. In reversing the District Court, the U.S. Court of Appeals for the Federal Circuit was clear that this "fact alone is not fatal to patentability." Id. Even though all of the elements of the device were admittedly "old" and "well-known" in the scrap industry, the Federal Circuit concluded that combining these features into a single device was not obvious. Id. Although the claimed invention may employ known principles, this does not in itself

establish that the invention would have been obvious. Id. Despite the clear desirability and commercial advantages of a single moderately sized scrap shear, the industry continued to process light and medium gauge metal separately from high gauge metal. It defies logic that the industry would have continued to do so if there truly was an “obvious” solution.

Just as in Lindemann, the elements of the claimed invention of the present Application have been cobbled together by the Examiner from admittedly old and well-known elements. The prior existence of the elements of a claim does not render the claim obvious. As best articulated by the former Chief Judge of the Federal Circuit, “virtually all inventions are ‘combinations’, and . . . every invention is formed of ‘old elements’ . . . Only God works from nothing. Man must work with old elements.” H.T. Markey, Why Not the Statute?, 65 J. Pat. Off. Soc’y 331, 333-34 (1983). The Examiner has failed to present any prior art reference which suggests combining or modifying the references as proposed by the Examiner. For this reason alone, the Examiner has failed to establish a prima facie case of obviousness.

Passage of time exhibits a trend away from the present invention

The Federal Circuit has held that it is proper to consider the “trend” in the art to show the obviousness of the inventor's solution. Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH, 139 F.3d 877, 45 USPQ2d 1977 (Fed. Cir. 1998). In this case there is a trend away from the present invention. The Lazure et al. reference was filed in 1976 and the Blass et al. article was submitted for publication in 1989. The Examiner claims that the Applicant’s invention is obvious to one of ordinary skill in the art, and yet is unable to present any reference that suggests the proposed modification or combination. Since 1976, hospitals and pharmacies, even though they were aware of the analgesic effect of sucrose, have chosen to hand mix analgesic agents and subject newborn infants to potentially inconsistent and unsanitary solutions. This, if anything, exhibits a trend away from the present invention. It defies logic to conclude that these skilled health care providers would continue utilizing an inefficient and potentially hazardous process if there was an “obvious” solution.

Mere recognition of the problem exhibits patentability

As articulated by the CCPA, “a patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the ‘subject matter as a whole’ which should always be considered in determining the obviousness of an invention under 35 USC 103.” In re Nomiya, 509 F.2d 566, 184 USPQ 607, 612 (C.C.P.A 1975). As discussed above, the Examiner has failed to demonstrate any suggestion or motivation to make the proposed combination. Moreover, this deficiency is for good reason, and can be easily explained. No one even recognized the problem let alone a solution to the problem. This is further proof that the present invention is non-obvious.

The Applicant contends that the Examiner has not met the burden to present a prima facie case of obviousness because there is no suggestion of the proposed combination, and there is not even any recognition of the problem. Instead, the Examiner appears to have given significant weight to the fact that the invention involves the combination of well-know elements and used inappropriate hindsight to cobble together the Applicant’s invention. Accordingly, the Applicant respectfully requests the Examiner to reconsider the rejection to claims 1-4, 6, 7, 10, 21, and 23-36.

The Examiner also rejected claims 12, 13, 15-17, 19, 20, 22, and 37-39 under 35 U.S.C. § 103 as being unpatentable over the applicant’s admission of the prior art as evidenced by the Blass et al. article, the Stevens et al. article dated 1997 (“the Stevens 1997 article”), the Stevens et al. article dated 1999 (“the Stevens 1999 article”), the Franck article, the Seattle Post-Intelligencer article, the Wisconsin State J. article, further in view of U.S. Patent No. 3,654,746 to Beckers, and U.S. Patent No. 4,597,242 to Hendriks et al., U.S. Patent No. 4,211,338 to Bublitz, further in view of U.S. Patent No. 2, 138,241 to Koch et al., U.S. Patent No. 4,165,594 to Corbic, U.S. Patent No. 4,875,620 to Lane, U.S. Patent No. 5,429,262 to Sharkey, U.S. Patent No. 3,390,766 to Stockdale, U.S. Patent No. 3,478,489 to Meisner, and U.S. Patent No. 3,414,414 to Christine et al., and further in view of the San Francisco Examiner article, New Food Products in Japan article, Food Engineering article.

As these references are the same references used in the previous rejection, the Applicant contends that they have the same deficiencies as noted above. Accordingly, the Applicant asserts the same arguments as recited above. Namely, the art failed to make, or even suggest, the Examiner's proposed combination of references. Secondly, the art does not even recognize the problem solved by the present invention. Claim 12 recites a method using single-use containers to hold a solution of sucrose and water for oral administration to a neonatal infant. Claim 17 recites a method of administering a sucrose solution from a sealed container. Claim 37 recites a method of producing a packaged sucrose solution in a sealed container. The references cited by the examiner simply do not disclose or suggest these methods.

## 2. Rebuttal of Prima Facie Case

Once the Examiner has established a prima facie case of obviousness, the burden shifts to the applicant to rebut the Examiner's case with objective evidence of nonobviousness. The applicant may present evidence relating to any of the secondary considerations outlined in Graham v. John Deere Co., 381 US 1, 148 USPQ 459 (1966) such as commercial success, fulfilling a long-felt need, failure of others, copying by others, and unexpected results. In addition, later opinions have added additional secondary considerations such as later discovered unexpected properties of the claimed invention, licenses or industry acquiescence, and skepticism prior to invention by those of ordinary skill. In re Mayne, 104 F.3d 1339, 41 USPQ 2d 1451 (Fed. Cir. 1997); Arkie Lures, Inc. v. Gene Larew Tackle, Inc., 119 F.3d 953, 43 USPQ 2d 1294, 1297 (Fed. Cir. 1997); In re Dow Chem. Co., 837 F.2d 469, 5 USPQ 2d 1529, 1532 (Fed. Cir. 1988).

The Applicant contends that introduction of the present invention into the marketplace has been met with surprising commercial success, resolves a long-felt need in the industry, and has been copied by at least one competitor. The Applicant sells an embodiment of the invention disclosed and claimed in the present application under the trademark SWEET-EASE™. A copy of the sales brochure for the SWEET-EASE™ product was previously submitted.

### Surprising Commercial Success

As outlined in the Declaration of Cathy N. Bush (previously presented), the SWEET-EASE™ product has had surprising commercial success. Ms. Bush compares the SWEET-EASE™ product with the HEEL HUGGER™ product. Both products are disposable, single-use products used on infants and sold by the Applicant. Even though the SWEET-EASE™ product has been in the industry for less than half as long, it achieved approximately six times as many sales in 2003. Ms. Bush attributes the surprising commercial success of the SWEET-EASE™ product to the fact that it provides a convenient, aseptically packaged container filled with a sucrose solution not previously available in the medical industry.

The Declaration of Ms. Bush was deemed by the Examiner as insufficient to overcome the prima facie case of obviousness. The Examiner states that it was unclear how effective the sole warmers were at providing pain relief. To provide some clarification, the sole warmers are another product used with infants and sold by the Applicant. The purpose is to warm the soles of the patients' feet to make the insertion of needles during various procedures less difficult and time consuming. Although this product may provide some relief, it is not an analgesic. These are two different products sold by the Assignee. The sole warmers were merely presented to provide a baseline for comparison purposes. Of course, it would be desirable to be able to compare the SWEET-EASE™ product with another comparable product. Unfortunately, the Applicant does not sell another packaged sucrose solution assembly. Rather than being used as a justification for discounting the persuasiveness of Ms. Bush's Declaration, it further exhibits the non-obviousness of the present invention.

### Long-felt need

The present invention fulfills a long-felt need in the industry. As described in the declarations (previously presented) of Don T. Granger, M.D., Neal Guttenberg, M.D., and M. David Yohannan, M.D. ("Physicians' Declarations"), hand-mixing sucrose solutions have been undesirable. Doing so may contaminate the solution, result in wasted time, and the creation of inconsistent solutions. This has been the status of the art for at least 15 years. Accordingly, it is clear that the present invention addresses a problem that has defied resolution. The Physicians'

Declarations describe the state of the art before introduction of the SWEET-EASE™ product and the long-felt need of neonatologists. The Physicians' Declarations also describe the impact that the SWEET-EASE™ product has had on the medical industry. The Physicians' Declarations, previously submitted, are merely a small sample of the declarations that the Applicant could provide. It should be noted that the Applicant could produce additional declarations if the Examiner requires additional support.

Copying by Others

It has recently come to the attention of the assignee of the present invention that at least one other company has begun advertising the availability of a product that is a copy of the Applicant's invention. As noted on the attached advertisement, Hawaii Medical, LLC advertises the availability of a product called the TootSweet™ 24% sucrose solution. The advertisement, among other things, states that this product "... helps to calm and soothe babies in distress and during painful procedures, while protecting against bacterial contamination." This is the same solution, in the same concentration, sold for the same purpose. Copying by others is yet another factor the Examiner is required to consider.

These arguments were previously presented in the Applicant's response dated May 4, 2005. The Examiner summarily dismissed these secondary considerations by stating that "[a]ll of the Applicant's remarks filed 5/4/05 have been fully and carefully considered but are not found to be convincing for the reasons of record which are considered to be clearly and fully detailed over the course of four Office actions." Notwithstanding the Examiner's position, the Applicant contends that it has met its burden by presenting not one but three secondary considerations. In light of the above noted secondary considerations in conjunction with the declarations and documents (previously submitted), independent claims 1, 12, 17, 23, 29, and 37, as well as all claims dependent thereon, are deemed to overcome the Examiner's rejections based upon 35 USC § 103.

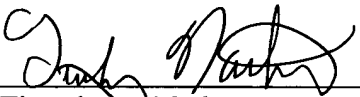
This response is being filed within three months after the three-month statutory response period which expired on October 13, 2005. No additional claim fees are believed to be required as a result of the above amendments to the claims. Nevertheless, the Commission is

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authorized to charge the three month extension fee as well as any other fee required under 37 C.F.R. §§ 1.16 or 1.17 to deposit account no. 50-0558.

All objections and rejections have been addressed. It is respectfully submitted that the present application is in condition for allowance and a Notice to the effect is earnestly solicited.

Respectfully submitted,

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